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UNITED STATES OF AMERICA

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11 UNITED STATES DISTRICT COURT
12 FOR THE CENTRAL DISTRICT OF CALIFORNIA
13 SOUTHERN DIVISION
14

15 UNITED STATES OF AMERICA,

16 Plaintiff,

17 v.

18 INNOVATIVE BIODEFENSE, INC.,
a corporation,
19 and COLETTE COZEAN, an individual,

20 Defendants.

No. CV XXXXXXXXX

COMPLAINT FOR PERMANENT
INJUNCTION

21
22 Plaintiff, the United States of America, by its undersigned attorneys, respectfully
23 represents to this Court as follows:

24 1. This statutory injunction proceeding is brought under the Federal Food,
25 Drug, and Cosmetic Act (the "Act"), 21 U.S.C. § 332(a), to permanently enjoin and
26 restrain Innovative BioDefense, Inc., a corporation, and Colette Cozean, an individual
27 (collectively, "Defendants") from:

28 ///

DEFENDANTS' OPERATIONS

7. Defendants cause the distribution of their Zylast products to customers outside of California.

8. Defendants operate the website www.zylast.com, which lists Innovative BioDefense's contact information under the hyperlink "Contact" and which includes the text "© 2015 Innovative BioDefense, Inc."

9. The physical labels on the Zylast products bear the text, "Manufactured for Innovative Biodefense Inc. . . . www.zylast.com." By clicking on a "Buy Now" icon at www.zylast.com, customers are taken to www.zylastdirect.com, where they can purchase the Zylast products.

10. The websites www.zylast.com and www.zylastdirect.com are hyperlinked to the Facebook page <https://www.facebook.com/ZylastXP>. In addition, www.zylastdirect.com is hyperlinked to the Twitter feed <https://twitter.com/ZylastXP>.

REQUIREMENTS OF THE ACT

11. A product is a drug within the meaning of the Act if, among other things, it is "intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man," 21 U.S.C. § 321(g)(1)(B).

12. The intended use of a product "refer[s] to the objective intent of the persons legally responsible for the labeling of drugs" and may be determined from any relevant source, including the circumstances surrounding the distribution of the article, product labeling, advertising, promotional material, or oral or written statements by such persons or their representatives. *See* 21 C.F.R. § 201.128.

13. The Act defines labeling as "all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article." 21 U.S.C. § 321(m). The term "accompanying" in the second clause of 21 U.S.C. § 321(m) is not restricted to labels that are on or in the article at issue; physical attachment to the article is not necessary. *See Kordel v. United States*, 335 U.S. 345, 349-50 (1948). It is the textual relationship and integrated nature of the transaction

1 that is significant. *See id.* at 350.

2 14. The Act prohibits, subject to the exception described in Paragraph 16
3 below, doing or causing the introduction or delivery for introduction into interstate
4 commerce of any new drug unless FDA has approved a new drug application (“NDA”)
5 or an abbreviated new drug application (“ANDA”) with respect to such drug, or such
6 drug is exempt from approval under an investigational new drug application (“IND”).
7 21 U.S.C. §§ 331(d) and 355(a), (b), (i), and (j). It is a violation of the Act to introduce
8 or deliver, or cause to be introduced or delivered, into interstate commerce a new drug
9 that is neither approved nor exempt from approval. 21 U.S.C. § 331(d).

10 15. A “new drug” is defined as any drug “the composition of which is such that
11 such drug is not generally recognized, among experts qualified by scientific training and
12 experience to evaluate the safety and effectiveness of drugs, as safe and effective for use
13 under the conditions prescribed, recommended, or suggested in the labeling thereof
14 ; or any drug . . . the composition of which is such that such drug, as a result of
15 investigations to determine its safety and effectiveness for use under such conditions, has
16 become so recognized, but which has not, otherwise than in such investigations, been
17 used to a material extent or for a material time under such conditions.” 21 U.S.C.
18 § 321(p).

19 16. FDA has established and published regulations, called “monographs,” that
20 describe certain categories of OTC drugs. OTC drugs manufactured and labeled in strict
21 conformance with final monographs are deemed to be “generally recognized as safe and
22 effective” (“GRAS/E”), 21 C.F.R. § 330.1, and can be marketed without FDA’s
23 premarket approval. Drugs that do not strictly conform to each of the conditions
24 contained in an applicable final monograph, however, are subject to the new drug
25 provisions of the Act. 21 C.F.R. § 330.10(b).

26 17. The Act also prohibits doing or causing the introduction or delivery for
27 introduction into interstate commerce of any drug that is misbranded. 21 U.S.C.
28 § 331(a).

1 18. A drug is misbranded within the meaning of 21 U.S.C. § 352(a) if its
2 labeling is false or misleading in any particular.

3 DEFENDANTS' VIOLATIONS OF THE ACT

4 Unapproved New Drugs

5 19. The Zylast products are drugs within the meaning of the Act because they
6 are intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease
7 in man. According to the Zylast products' labeling, including information and
8 hyperlinks on www.zylast.com and www.zylastdirect.com, and the Facebook and
9 Twitter pages referenced in paragraph 10, the Zylast products are intended to be used as
10 topical antiseptics that are effective against the stomach flu and the common cold, and
11 against infection by pathogens that include, but are not limited to, norovirus, rhinovirus,
12 rotavirus, flu virus, Methicillin-Resistant Staphylococcus Aureus bacteria, and/or Ebola
13 virus. In addition, as late as June 19, 2017, the Zylast products' labeling also contained
14 claims that they were effective against H1N1, HIV, herpes, and Vancomycin-resistant
15 enterococci bacteria.

16 20. Defendants' Zylast products are not GRAS/E for their intended uses
17 because there are no published adequate and well-controlled clinical studies
18 demonstrating that Defendants' Zylast products are generally recognized as safe and
19 effective for their intended uses, nor are they the subjects of safety investigations
20 resulting in such recognition, nor have they been used for a material extent or time under
21 such conditions. Therefore, the Zylast products are new drugs within the meaning of 21
22 U.S.C. § 321(p).

23 21. Defendants' Zylast products also do not conform to any applicable final
24 OTC monograph and, accordingly, are subject to the new drug provisions of the Act,
25 including the provisions requiring premarket approval.

26 22. Defendants' Zylast products lack an approved NDA or an approved ANDA
27 as required by 21 U.S.C. § 355(b) or (j), respectively, and are not exempt from approval
28 pursuant to an effective IND under 21 U.S.C. § 355(i).

shipment constitutes the introduction or delivery for introduction of unapproved new drugs and misbranded drugs into interstate commerce under 21 U.S.C. §§ 331(a) and (d).

HISTORY OF VIOLATIONS

27. Defendants have repeatedly violated the Act and such noncompliance has continued in the face of repeated warnings from FDA that Defendants' conduct violates the law and that continued violations could lead to regulatory action.

28. In a June 30, 2015, Warning Letter to Defendants, FDA described Defendants' violations and notified Defendants that continued violations could lead to regulatory action, including an injunction.

29. Defendants responded in writing on July 6, 10, and 16, 2015. However, as FDA pointed out in a follow-up letter to Defendants dated August 12, 2015, Defendants' responses did not address the violations described in the Warning Letter.

30. In addition, FDA previously held a meeting with Defendants on March 31, 2015, and corresponded with Defendants by letter dated June 15, 2015, which informed Defendants of the agency's view on the legal status of their drug products and their obligation to comply with the Act's premarket approval requirement.

31. To date, Defendants have not filed an NDA, ANDA, or IND for the Zylast products and continue to cause the distribution of these unapproved new drugs and misbranded drugs in interstate commerce.

32. Accordingly, unless restrained by this Court, Defendants will continue to violate the Act, 21 U.S.C. §§ 331(a) and (d), in the manner set forth above.

WHEREFORE, the United States respectfully requests that the Court:

I. Permanently restrain and enjoin, under 21 U.S.C. § 332(a), Defendants, and each and all of their directors, officers, agents, representatives, employees, attorneys, successors, and assigns, and any and all persons in active concert or participation with any of them, from directly or indirectly doing or causing to be done any of the following acts:

///

1 A. Violating 21 U.S.C. § 331(d), by introducing or delivering, or causing
2 to be introduced or delivered, into interstate commerce unapproved new drugs; and

3 B. Violating 21 U.S.C. § 331(a), by introducing or delivering, or causing
4 to be introduced or delivered, into interstate commerce drugs that are misbranded within
5 the meaning of 21 U.S.C. § 352(a).

6 II. Permanently restrain and enjoin, under 21 U.S.C. § 332(a), Defendants, and
7 each and all of their directors, officers, agents, representatives, employees, attorneys,
8 successors, and assigns, and any and all persons in active concert or participation with
9 any of them, from directly or indirectly introducing or delivering for introduction, or
10 causing to be introduced or delivered for introduction, into interstate commerce any
11 drug, including but not limited to the Zylast products and any product labeled similarly
12 to such products and containing the same active ingredients, unless and until:

13 A. An approved NDA, ANDA, or an IND application Defendants filed
14 pursuant to 21 U.S.C. §§ 355(b), (j), or (i), is in effect for such drugs, or Defendants
15 have removed all claims from their product labels, labeling, promotional materials,
16 websites owned or controlled by or related to Defendants, and in any other media that
17 cause any of Defendants' products to be a new drug within the meaning of the Act; and

18 B. Defendants have removed all claims from their product labels,
19 labeling, promotional materials, websites owned or controlled by or related to
20 Defendants, and in any other media that cause any of Defendants' products to be
21 misbranded within the meaning of the Act.

22 III. Order that FDA be authorized to inspect Defendants' place(s) of business
23 and all records relating to the receipt, manufacture, processing, packing, labeling,
24 holding, and distribution of any of Defendants' products to ensure continuing
25 compliance with the terms of the injunction, the costs of such inspections to be borne by
26 Defendants at the rates prevailing at the time the inspections are accomplished.

27 IV. Grant judgment for Plaintiff's costs herein, and such other and further relief
28 as the Court deems just and proper.

1 DATED this 6th day of June, 2018.

2 Respectfully submitted,

3 Of Counsel:

/s/ Douglas Ross

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